UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

DENISE OCASIO and CARMELO OCASIO,

Plaintiffs,

v. Case No: 8:13-cv-1962-T-36AEP

C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,

Defendants.
_____/

ORDER

This cause comes before the Court upon the Motion for Summary Judgment filed by Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard") (Doc. 48). Plaintiffs Denise Ocasio and Carmelo Ocasio (collectively, "Plaintiffs") responded in opposition to the Motion (Doc. 67), and Bard replied in further support of its Motion (Doc. 80). Bard also filed a Motion to Strike Plaintiffs' Untimely Expert Opinions of Drs. Begley and Hyman (Doc. 74), to which Plaintiffs responded in opposition (Doc. 83). The parties submitted a number of supplemental authorities (Docs. 82, 104, 125, 128, 131). The Court held oral argument on the Motions on February 20, 2015. Doc. 113. The Court, having considered the parties' submissions and being fully advised in the premises, will now DENY Bard's Motion to Strike and GRANT-IN-PART and DENY-IN-PART Bard's Motion for Summary Judgment.

I. STATEMENT OF FACTS[1]

This litigation arises from injuries suffered by Denise Ocasio when her implanted inferior vena cava ("IVC") filter perforated her IVC. Ms. Ocasio has a history of severe inflammatory bowel disease ("IBD"). Doc. 48-3 ("Ocasio Dep.") at 41. IBD is known to be associated with an increased tendency for blood clotting. Doc. 48-4 ("Back Dep.") at 26-27. In April 2010, Ms. Ocasio was diagnosed with a pulmonary embolism after she went to the emergency room complaining of shortness of breath and "a really bad pain" in her chest. Ocasio Dep. at 62-63, 68-69. Because pulmonary embolisms are a well-recognized cause of sudden death, an IVC filter was implanted into Ms. Ocasio by Dr. Bruce Zweibel shortly thereafter to prevent additional pulmonary embolisms. Docs. 48-1 ("Grassi Rpt.") at 2; 48-6; 48-2 ("Zweibel Dep.") at 35-36.

The filter that was implanted in Ms. Ocasio was a Bard G2 filter. Doc. 48-6. The G2 filter consists of two tiers of struts that make up its arms and legs. Once deployed, the filter's arms and legs open and anchor it to the walls of the IVC. The filter then catches blood clots that could otherwise flow into the heart and lungs as pulmonary emboli. Grassi Rpt. at 2. The filter is an optional filter, which means that it can be removed percutaneously after implantation, but is designed to act as a permanent IVC filter. Doc. 48-16 ("IFU") at 1.

In late 2010, Ms. Ocasio began experiencing pain in her right leg. Ocasio Dep. at 89, 98. By June 2011, she was experiencing sharp pains and numbness in her right leg. *Id.* In December of 2011, she went to the emergency room regarding the leg pain. *Id.* at 96-97. She was sent home with no reason identified for the leg pain. *Id.* at 102. Her IVC filter was not discussed during her visit. *Id.*

[1] The Court has determined the facts, which are undisputed unless otherwise noted, based on the parties' submissions, stipulated facts, affidavits, and deposition testimony.

By February 2012, Ms. Ocasio's right leg pain had worsened, her foot was swollen and bruised, and her leg was numb. *Id.* at 103-04. Arterial Doppler scans were performed, revealing extensive blood clots in the arterial system of her right leg. Doc. 48-7. A CT scan revealed that a strut of the IVC filter had perforated her IVC and into her aorta, and that thrombus was present at its tip. Back Dep. at 47-48. Ms. Ocasio's treating physicians concluded that the strut perforating her aorta with the clot at its tip was the source of the blood clotting in her right leg. Doc. 48-7. Ms. Ocasio subsequently underwent surgery to clip the perforating strut, as well as several surgeries on her right leg to clear the clotting. *Id.*; Doc. 48-8. To this day, Ms. Ocasio's IVC filter remains implanted. Doc. 48-7; Back Dep. at 88.

Plaintiffs assert the following causes of action: (1) negligence; (2) strict products liability – failure to warn; (3) strict products liability – design defects; (4) strict products liability – manufacturing defect; (5) breach of implied warranty of merchantability; (6) negligent misrepresentation; and (7) loss of consortium. Plaintiffs seek, *inter alia*, compensatory and punitive damages.

Bard now moves for summary judgment as to all of Plaintiffs' causes of action, as well as to Plaintiffs' claim for punitive damages. In response, Plaintiffs state that they will withdraw their cause of action for a breach of implied warranty of merchantability, but otherwise oppose the Motion. *See* Doc. 67 at 9. The Court will therefore grant Bard's Motion as to the Fifth cause of action, and will address the remaining issues below.

II. LEGAL STANDARD

Summary judgment is appropriate when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed.

R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The moving party bears the initial burden of stating the basis for its motion and identifying those portions of the record demonstrating the absence of genuine issues of material fact. *Celotex*, 477 U.S. at 323; *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1259-60 (11th Cir. 2004). That burden can be discharged if the moving party can show the court that there is "an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325.

When the moving party has discharged its burden, the nonmoving party must then designate specific facts showing that there is a genuine issue of material fact. *Id.* at 324. Issues of fact are "genuine only if a reasonable jury, considering the evidence present, could find for the nonmoving party," and a fact is "material" if it may affect the outcome of the suit under governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). In determining whether a genuine issue of material fact exists, the court must consider all the evidence in the light most favorable to the nonmoving party. *Celotex*, 477 U.S. at 323. However, a party cannot defeat summary judgment by relying upon conclusory allegations. *See Hill v. Oil Dri Corp. of Ga.*, 198 Fed. App'x 852, 858 (11th Cir. 2006).

III. DISCUSSION

A. Motion to Strike

At the outset, Bard argues that, pursuant to Federal Rule of Civil Procedure 37, the Court should strike the "new" expert opinions of Drs. Begley and Hyman contained in their respective affidavits submitted by Plaintiffs in support of their opposition to Bard's Motion for Summary Judgment. Federal Rule of Civil Procedure 26 governs the disclosure of expert witnesses, and requires a party to provide "a complete statement of all opinions" offered by an expert witness and "the basis and reasons for them" "at the times and in the sequence that the court orders." Fed. R.

Civ. P. 26(a)(2)(B) & (D). Rule 37 provides that if a party fails to conform to the disclosure requirements of Rule 26(a), the proffered information must be excluded "unless the failure [to disclose] was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). In other words, if an expert opinion is not disclosed in accordance with the scheduling order, it may be excluded under Rule 37. *See Corwin v. Walt Disney Co.*, 475 F.3d 1239, 1252 (11th Cir. 2007).

With regard to Dr. Hyman, Bard seeks to strike only a single "new" opinion in his affidavit—that "[a] proper warning . . . should have included the comparative risk information that was available to Bard . . . so the physician could effectively weigh the utility of the particular device versus the actual risk it presents," Ex. 12 to Doc. 67 ("Hyman Aff.") at 37. The Court, however, need not decide whether this opinion should be stricken under Rule 37, because, in ruling on Bard's *Daubert*[2] motions, it concluded that Dr. Hyman is not qualified to opine as to the adequacy of the G2 filter's labeling. *See Ocasio v. C.R. Bard, Inc.*, Case No. 8:13-cv-1962, 2015 WL 2062611, at *3 (M.D. Fla. May 4, 2015) ("[T]he Court here concludes that Hyman's limited experience [with labeling requirements] fails to qualify him as an expert on the adequacy of the labeling of the G2 filter."). Accordingly, because all of Dr. Hyman's labeling opinions, including the one challenged in Bard's Motion to Strike, are already due to be excluded under *Daubert*, the Court will deny as moot Bard's Motion to Strike to the extent it relates to this opinion.

With regard to Dr. Begley, Bard seeks to exclude the "more than thirty pages of new opinions, formulas, calculations, tables, and other material" contained in his affidavit, such as modeling, calculations, and opinions regarding the effects of perforation on the fatigue of Bard's Recovery[3] and G2 filters as well as the stress and strain experienced by the G2 filter in relation to

[2] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).
[3] The Recovery filter is the predecessor filter to the G2 filter. *See* Doc. 131 ("Hull Rpt.") at 2.

the Recovery filter, *see* Ex. 37 to Doc. 67 ("Begley Aff.") at 26-34. Bard argues that Begley's affidavit goes far beyond both his initial report and his deposition testimony, and that these opinions are highly prejudicial to Bard because they were offered only after the close of expert discovery and after Bard had already filed its Motion for Summary Judgment. Bard adds that Plaintiffs can offer no substantial justification for the late disclosure of these opinions because Plaintiffs' counsel was aware of these opinions well before the close of discovery, as these opinions were rendered in the course of another case involving the same counsel, *Leus v. C. R. Bard, Inc.*, 4:13-cv-585 (W.D. Mo.) (hereinafter, "*Leus*").

In response, Plaintiffs contend that the "new" information in Begley's affidavit simply provides additional evidentiary details for the opinions expressed in his initial expert report. Plaintiffs add that, even assuming that these opinions were "new," the modeling supporting these new opinions was completed only after Begley had been deposed, and Plaintiffs' lead counsel was not aware of this testing when it was performed and did not become aware of it until after Bard filed its Motion for Summary Judgment. Plaintiffs note that Bard, on the other hand, was well aware of this additional testing several weeks before it filed its Motion for Summary Judgment, because the additional testing and opinions had been disclosed to Bard in *Leus* at that time. Thus, according to Plaintiffs, even assuming that the opinions and information contained in Begley's affidavit were new and untimely disclosed, any delay in their disclosure was substantially justified and/or harmless. Plaintiffs argue that, in any case, exclusion is unwarranted because they will permit Begley to be re-deposed and Bard to designate a rebuttal witness if necessary.

After carefully considering the parties' arguments, the Court determines that the exclusion of the opinions contained in Begley's affidavit is unwarranted. Indeed, given Bard's prior knowledge of the same opinions in *Leus*, the prejudicial effect, if any, of introducing these opinions

at this stage in the litigation is greatly diminished. Moreover, there is no evidence that, in introducing these opinions at this stage of the litigation, Plaintiffs were attempting to employ any bad faith "gotcha" tactics that Rule 37 was intended to prevent. The Court recognizes, however, that there may nevertheless be some prejudice to Bard as a result of the late disclosure of these opinions in this case. The Court will therefore remedy any potential prejudice by ordering Plaintiffs to produce Begley for an additional deposition on the information and opinions contained in his affidavit, and permitting Bard to designate a rebuttal expert if necessary.[4] *Accord St. Cyr v. Flying J Inc.*, Case No. 06-cv-13, 2007 WL 2936243, at *4 (M.D. Fla. Oct. 9, 2007) (where the plaintiffs failed to timely provide an expert report, noting that, "[a]lthough this Court would be justified in striking [the expert] report and disallowing [the expert] testimony . . . . [w]itness preclusion is a harsh sanction that should be imposed sparingly and only when other sanctions are unavailable," and instead permitting the defendant to re-depose the expert prior to trial).

B. Failure to Warn (First and Second Causes of Action)

To establish a strict products liability claim for failure to warn, a plaintiff must prove that the defendant manufactured or distributed the product at issue, but did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture or distribution. *See Thomas v. Bombardier Recreational Prods., Inc.*, 682 F. Supp. 2d 1297, 1300 (M.D. Fla. 2010). With regard to a manufacturer of medical devices, the learned intermediary doctrine applies, and the duty to warn attaches to the patient's physician rather than to the patient directly. *See Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989); *see also Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. 1st DCA 2009). Moreover, even if the manufacturer has failed to

[4] This issue will be addressed at a telephonic status conference to be scheduled by the Court.

give the physician an adequate warning, the manufacturer cannot be held liable for the patient's injury if the physician had independent knowledge of the risk that the adequate warning should have communicated. *See Felix*, 540 So. 2d at 105.

Bard contends that Plaintiffs' failure to warn claims fail because it adequately warned Dr. Zweibel of the risk of relevant complications in the G2 filter, and that Dr. Zweibel had independent knowledge of the G2 filter's risks. Specifically, Bard points to the IFU in effect at the time of Ms. Ocasio's operation, which lists "[p]erforation or other acute or chronic damage of the IVC wall," "[v]essel injury," and "[o]rgan injury" as "Potential Complications" of the G2 filter, IFU at 3, and Dr. Zweibel's deposition testimony that the language of the IFU was clear to him as a physician, Zweibel Dep. at 26-27. Bard also points to Dr. Zweibel's deposition testimony that, prior to implanting the G2 filter in Ms. Ocasio, he generally knew that perforation of the IVC was a risk associated with the G2 filter, *id.* at 23-24, 33-34, and he was aware of medical literature finding that perforation of the IVC by IVC filters can occur in up to 41% of patients, *id.* at 21-23.

In response, Plaintiffs do not dispute that the IFU does not contain any affirmative misstatements or that Dr. Zweibel understood it from a medical perspective. Rather, Plaintiffs contend that the IFU was inadequate because Bard should have additionally provided quantitative comparative failure rates. Plaintiffs also argue that Dr. Zweibel did not have adequate independent knowledge of the risks of the G2 filter due to Bard's failure to make such information available.

After careful consideration, the Court agrees with Bard that Plaintiffs' failure to warn claims must fail, because there is no evidence that the IFU failed to adequately apprise Dr. Zweibel of the dangers of the G2 filter, including its risk for perforation. To begin with, it is not obvious whether the IFU's lack of quantitative comparative failure rates renders it inadequate. In such

situations, "the adequacy or inadequacy of the warning to inform a physician must . . . be proved by expert testimony." *Upjohn Co. v. MacMurdo*, 562 So. 2d 680, 683 (Fla. 1990).

Plaintiffs have failed to provide any admissible expert testimony that would establish the inadequacy of the IFU. Plaintiff's purported labeling expert, Dr. Hyman, has been excluded under *Daubert* as not qualified to offer his opinions regarding the labeling of the G2 filter. *See Ocasio*, 2015 WL 2062611, at *3. Further, although Plaintiffs note that Dr. Zweibel testified that he would have liked to have comparative failure rates, *see, e.g.*, Zweibel Dep. at 85-86; and that such information would have been helpful to him in weighing the risks and benefits of the device, *see, e.g.*, *id.* at 87, this testimony establishes, at most, only that additional information would have given him *better* warning, but fails to establish that the IFU was actually *inadequate* in informing him of the risks of the G2 filter.[5]

Accordingly, the Court will grant Bard's Motion for Summary Judgment to the extent it relates to Plaintiffs' failure to warn claims.[6] *Accord MacMurdo*, 562 So. 2d at 683 (granting summary judgment as to failure to warn claim where "no medical expert testified that the package insert was insufficient to put a doctor on notice that the symptoms displayed by [the plaintiff] . . . could result from the use of [the drug]"); *Tillman v. C.R. Bard, Inc.*, Case No. 13-cv-222, 2015 WL 1456657, at *23 (M.D. Fla. Mar. 30, 2015); *compare Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1517 (S.D. Fla. 1990) (where the warning supplied with a drug failed to present data

[5] Plaintiffs also assert that Dr. Zweibel agreed that the IFU provided "little assistance to the care provider in assessing the risks and benefits of the device's use." Doc. 67 at 12. However, Plaintiffs overstate the deposition testimony, which suggests, at the very most, that having a comparative analysis would be more beneficial than having a simple list of possible failure modes (but does not establish that such analysis is necessarily required to give adequate warning). *See* Zweibel Dep. at 57.

[6] Because there is no evidence that the warning was inadequate, the Court need not (and does not) decide whether Dr. Zweibel had adequate independent knowledge of the risks of the G2 filter.

that would allow a physician to make a judgment as to the comparative risk of complications, denying summary judgment as to failure to warn claim because the plaintiff's expert testified that the warning was inadequate for that reason).

C. Design Defects (First and Third Causes of Action)

Bard contends that the design defect claims fail for three reasons. *First*, Bard argues that comment k to Section 402A of the Restatement (Second) of Torts (hereinafter, "comment k") applies, thus converting the design defect claims into failure to warn claims. *Second*, Bard argues that even if comment k did not apply, the design defect claims still fail because there is no evidence as to what was defective about Ms. Ocasio's filter or how any such defect caused the filter to perforate Ms. Ocasio's IVC. *Finally*, Bard argues that there is no evidence of a reasonable alternative design, thus precluding a claim for design defect. None of these arguments are persuasive.

First, there is a genuine issue of material fact whether comment k applies here. Comment k shields a manufacturer from strict products liability for an "unavoidably unsafe product" if the product was "properly prepared, and accompanied by proper directions and warning." Comment k. Under Florida law, comment k may be raised as an affirmative defense to a strict liability design defect claim for a medical device. *See Adams v. G.D. Searle & Co., Inc.*, 576 So. 2d 728, 733 (Fla. 2d DCA 1991). Notably, comment k applies only to "a product which is as safe as current testing and research permits . . . ." *Id.* at 732. Conversely, "a product which is not as safe as current technology can make it should not be protected." *Id.* Moreover, comment k applies only where "the product's benefits [] outweigh its known risks as of the date the product [was] distributed." *Id.* at 733.

Bard asserts that it is undisputed that IVC filters are life-saving devices, and that they all carry risks of serious injury, including perforation. *See, e.g.*, Zweibel Dep. at 13-14. However, Bard fails to address whether the G2 filter was as safe as current testing and research permitted or whether its benefits outweighed its known risks—and, as Plaintiffs contend, the evidence reveals that the G2 filter was far from being as safe as it could have been made. For example, according to one of Plaintiffs' experts, Dr. Michael Freeman, the failure rate of the G2 filter was far higher than both retrievable and permanent filters not manufactured by Bard. *See* Ex. 9 to Doc. 67-1 ("Freeman Aff.") at 4-5. Similarly, according to Dr. Begley, Bard should have conducted additional testing and analysis on the effects of *in situ* loading on the filter, which presumably would have resulted in a safer filter. *See* Begley Aff. at 5-8, 56. Because there is a genuine dispute whether the G2 filter was as safe as it could have been made as well as whether its benefits outweighed its known risks, Bard cannot prevail, as a matter of law, as to the application of comment k. *Accord Tillman*, 2015 WL 1456657, at *27-29.

Second, although Plaintiffs may not have pinpointed any one design factor of the G2 filter that specifically caused Ms. Ocasio's filter to perforate, Plaintiffs have presented evidence that the *overall design* of the filter was unreasonably dangerous as it related to the injuries suffered by Ms. Ocasio. *See, e.g.*, Freeman Aff. at 5 ("The [G2 filter] is associated with perforation of the inferior vena cava 2.9 and 5.0 times more often than the competitors' retrievable and permanent filters, respectively."); Begley Aff. at 56 ("Bard underestimated the risk of perforation as a result of (i) erroneous assumptions . . . and (ii) inadequate analysis . . . ."). This is sufficient to create a triable issue as to whether the G2 filter's allegedly defective design caused Ms. Ocasio's past, ongoing, and future injuries. *Accord Tillman*, 2015 WL 1456657, at *33.

Finally, even assuming *arguendo* that Plaintiffs have not offered any evidence of a reasonable alternative design, such evidence is not required under Florida law. In support of its argument that such a requirement exists, Bard relies on *Union Carbide Corp. v. Aubin*, 97 So. 3d 886, 894 (Fla. 3d DCA 2012), in which the Florida Third District Court of Appeal held that Section 2 of the Restatement (Third) of Torts is binding law in that district. *See* Restatement (Third) of Torts, Section 2 ("A product . . . is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a *reasonable alternative design* . . . and the omission of the alternative design renders the product not reasonably safe.") (emphasis added).

As noted by the Fourth District Court of Appeal, however, this standard has "not yet been adopted in Florida." *Liggett Grp., Inc. v. Davis*, 973 So. 2d 467, 473 (Fla. 4th DCA 2007). Rather, aside from the Third District Court of Appeal, it appears that evidence of a reasonable alternative design is but "one factor which can be demonstrated and argued to the jury." *Id.* at 475; *see also Kaufman v. Wyeth LLC*, Case No. 02-cv-22692, 2011 WL 10483576, at *6 (S.D. Fla. Aug. 15, 2011); *Radiation Tech., Inc. v. Ware Constr. Corp.*, 445 So. 2d 329, 331 (Fla. 1983) (holding that the availability of "other, safer products" is but one factor to consider in evaluating whether a product is unreasonably dangerous). Finally, even to the extent such a standard applies, it has yet to be extended by any Florida court to the context of medical devices. *See Tillman*, 2015 WL 1456657, at *31 ("The Florida cases in which courts have applied or acknowledged the test set forth in section 2 of the Third Restatement did not concern pharmaceutical drugs or medical devices. . . . This is significant because the Third Restatement actually contains a separate provision specifically tailored to medical devices."). The Court thus agrees with the *Tillman* court's holding that "the reasonable alternative design test advocated by Bard is not the appropriate

standard for a medical device case such as this," *id.*, and, accordingly, will not grant summary judgment as to the design defect claims on this ground.

In sum, there exists a genuine issue of material fact as to whether the risk of danger in the G2 filter's design outweighed its benefits. The Court, therefore, will deny Bard's Motion for Summary Judgment to the extent it relates to Plaintiffs' design defect claims.[7]

D. Manufacturing Defect (First and Fourth Causes of Action)

To establish a claim for a manufacturing defect, a plaintiff must prove that the product departed from its intended design such that it failed to perform as safely as the intended design would have performed. *See Citizens Property Ins. Corp. v. Simkar LLC*, 813 F. Supp. 2d 1356, 1363 (M.D. Fla. 2011). As distinguished from a design defect claim, a claim for manufacturing defect is based on "aberrational" defects and not those that occur throughout an entire line of products. *See Benitez v. Synthes, Inc.*, 199 F. Supp. 2d 1339, 1344 (M.D. Fla. 2002). In other words, "the distinction is between an unintended configuration [a manufacturing defect], and an intended configuration that may produce unintended and unwanted results [a design defect]." *Id.* A plaintiff must demonstrate that the manufacturing defect existed at the time it left the defendant's plant. *See Beauregard v. Continental Tire N. Am., Inc.*, 435 Fed. App'x 877, 879 (11th Cir. 2011).

[7] Bard also suggests, in passing, that it is entitled to a rebuttable presumption of no liability because the G2 filter complied with federal safety regulations. *See* Doc. 48 at 15 and n.3; Fla. Stat. § 768.1256(1) ("In a product liability action . . . there is a rebuttal presumption that the product is not defective or unreasonably dangerous and the manufacturer or seller is not liable if, at the time the specific unit of the product was sold . . . the aspect of the product that allegedly caused the harm [c]omplied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or injury . . . ."). However, as Plaintiffs note, Bard has utterly failed to explain how the G2 filter complied with all relevant "federal or state codes, statute, rules, regulations, or standards," so the Court declines to attach any such presumption. *Accord Kaufman*, 2011 WL 10483576, at *7.

Bard argues that the manufacturing defect claims fail because Plaintiffs have set forth no evidence that the filter implanted in Ms. Ocasio varied from the other G2 filters in its lot. In response, Plaintiffs assert that because the perforation arose out of the normal use of the G2 filter, they are entitled to an inference of manufacturing defect as discussed in *Cassisi v. Maytag Co.*, 396 So. 2d 1140 (Fla. 1st DCA 1981). Plaintiffs add that the filter failed to perform as safely as its intended design would have performed, and that Ms. Ocasio's filter had become dysfunctional and thus unable to perform as designed.

The Court agrees with Bard that Plaintiffs have not created a triable issue of fact as to the existence of a manufacturing defect. To begin with, Plaintiffs are not entitled to a *Cassisi* inference. Under *Cassisi*, a plaintiff is entitled to an inference of a manufacturing defect if the product malfunctioned during the course of normal operations. *See Cassisi*, 396 So. 2d at 1146. However, not every complication constitutes a "malfunction"—rather, a malfunction must be a failure that would not have occurred "but for" the existence of a manufacturing defect. *See Beauregard*, 435 Fed. App'x at 880. In other words, the inference of a manufacturing defect arises only if an event occurs that, "based on the design of the unit, [] should not have [occurred]." *Edic v. Century Prods. Co.*, 364 F.3d 1276, 1285-86 (11th Cir. 2004); *see, e.g.*, *Cassisi*, 396 So. 2d at 1146 (inference of manufacturing defect where clothes dryer caught on fire).

Here, the evidence is undisputed that perforation is a risk inherent in the design of all IVC filters, including (and, perhaps, especially for) the G2 filter. *See, e.g.*, Zweibel Dep. at 23-24 ("Q: [D]o you believe that the risk of penetration of the inferior vena cava and other adjacent body structures by IVC filter struts was known generally among the community of doctors who placed IVC filters? . . . [A]: I think generally speaking, yes."); Freeman Aff. at 5 ("The [G2 filter] is associated with perforation of the inferior vena cava 2.9 and 5.0 times more often than the

competitors' retrievable and permanent filters, respectively."). Therefore, the mere fact that Ms. Ocasio's filter perforated her IVC is insufficient to establish that it malfunctioned. Plaintiffs offer no evidence that Ms. Ocasio's injury differed in any way from the multitude of well-documented injuries observed to have been caused by the G2 filter. Accordingly, Plaintiffs are not entitled to a *Cassisi* inference.

Plaintiffs' other points are also not well-taken. Plaintiffs assert that Ms. Ocasio's filter failed to perform as safely as its intended design would have performed, but offer no evidence as to how the intended design of the G2 filter would have performed.[8] Notably, this assertion is undermined by Plaintiffs' design defect claims, which are premised on the allegation (now supported by evidence) that the G2 filter's intended design resulted in much higher incidences of perforation than other IVC filters. Similarly, the fact that Ms. Ocasio's filter suffered a complication rendering it unable to perform its function is irrelevant to the existence of a manufacturing defect, aside from potentially supporting a *Cassisi* inference. But, as discussed in detail above, Plaintiffs are not entitled to such an inference.

At bottom, Plaintiffs simply have not offered any evidence that Ms. Ocasio's filter was "aberrational" in any way. Accordingly, the Court will grant Bard's Motion for Summary Judgment as it relates to Plaintiffs' manufacturing defect claims.

E. Negligent Misrepresentation (Sixth Cause of Action)

A claim for negligent misrepresentation requires a plaintiff to prove that "(1) there was a misrepresentation of material fact; (2) the representer either knew of the misrepresentation, made

[8] In making this argument, Plaintiffs appear to conflate the concept of "how the *intended design* would have performed" with the concept of "how the design *was intended* to perform." It is obvious that no manufacturer would intend for its product to suffer a complication or failure. Accordingly, if the product's performance were compared to how its design *was intended* to perform, *every failure* would result in a manufacturing defect claim.

the misrepresentation without knowledge of its truth or falsity, or should have known the representation was false; (3) the representer intended to induce another to act on the misrepresentation; and (4) injury resulted to a party acting in justifiable reliance upon the misrepresentation." *Gallon v. Geico Gen. Ins. Co.*, 150 So. 3d 252, 254 (Fla. 2d DCA 2014) (quotation marks and citations omitted).

Bard argues that Plaintiffs' negligent misrepresentation claim fails as a matter of law because Plaintiffs have failed to identify any misrepresentation that it made to either Ms. Ocasio or Dr. Zweibel. Bard adds that, even if Plaintiffs were able to establish that it made a misrepresentation to Dr. Zweibel, Dr. Zweibel did not justifiably rely on any such misrepresentation due to his longstanding, independent knowledge of the risks associated with the Bard filter and IVC filters.

The Court agrees with Bard, because there is no evidence of any misrepresentation made by Bard upon which Dr. Zweibel relied, justifiably or otherwise. Plaintiffs contend that certain of Bard's online webpages touting the benefits of the G2 filter contain misrepresentations, and assert in a conclusory manner that those misrepresentations were made "to the medical community, including Dr. Zweibel." Doc. 67 at 25-26. However, Plaintiffs point to no evidence that Dr. Zweibel actually relied upon those purported misrepresentations, or that he even ever saw them. Indeed, Dr. Zweibel's deposition testimony establishes only that he might have chosen a different device to implant in Ms. Ocasio had he been made aware of *additional* studies and data relating to the G2 filter, of which he was unaware at the time he implanted the device. *See* Zweibel Dep. at 124. Bard's alleged failure to provide additional truthful information does not satisfy any element of negligent misrepresentation; to the contrary, Plaintiffs must establish that Bard made an *affirmative misrepresentation* upon which Dr. Zweibel justifiably relied. *See Gallon*, 150 So. 3d

at 254. At this stage in the proceedings, after the parties have already had the full opportunity to conduct extensive discovery, it would be unreasonable to infer from the mere existence of the webpages that Dr. Zweibel actually saw those webpages and then justifiably relied upon them in making his decision to implant the G2 filter in Ms. Ocasio.

Plaintiffs note that justifiable reliance is not a necessary element of fraudulent misrepresentation. Plaintiffs' point misses the mark, however, because Plaintiffs have alleged only a cause of action for *negligent* misrepresentation—a distinct and separate cause of action with different elements and a different standard of proof, *see Specialty Marine & Indus. Supplies, Inc. v. Venus*, 66 So. 3d 306, 310 (Fla. 1st DCA 2011). Plaintiffs' attempt to amend their Complaint via their response to Bard's Motion for Summary Judgment is plainly improper, and the Court declines to consider it. *See Gilmour v. Gates, McDonald & Co.*, 382 F.3d 1312, 1315 (11th Cir. 2004) ("A plaintiff may not amend her complaint through argument in a brief opposing summary judgment").

For the reasons stated above, Bard is entitled to summary judgment as to Plaintiffs' claim for negligent misrepresentation.

F. Punitive Damages

Under Florida law, a defendant may be held liable for punitive damages only if there is "clear and convincing evidence" that "the defendant was personally guilty of intentional misconduct or gross negligence." Fla. Stat. § 768.72(2). "'Intentional misconduct' means that the defendant had actual knowledge of the wrongfulness of the conduct and the high probability that injury or damage to the claimant would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage." Fla. Stat. § 768.72(2)(a). "'Gross negligence' means that the defendant's conduct was so reckless or wanting in care that it

constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct." Fla. Stat. § 768.72(2)(b). The misconduct "must bear a relationship to the fact of injury or invasion of legal right." *Smith v. Vining*, 407 So. 2d 1048, 1049 (Fla. 3d DCA 1981).

Bard argues that Plaintiffs are not entitled to punitive damages because, according to Bard, Plaintiffs cannot provide any "clear and convincing" evidence that Bard had actual knowledge that the G2 filter would cause Ms. Ocasio to develop her alleged injuries, or that Bard acted in a grossly negligent manner with regard to Ms. Ocasio's injuries.[9] In response, Plaintiffs contend that the evidence establishes that Bard knew of the dangerousness of the G2 filter, but nevertheless continued to market it without making feasible modifications or making adequate disclosures of such data.

The Court finds that Plaintiffs have set forth evidence sufficient to establish a triable issue of fact with regard to punitive damages. To begin with, there is evidence that, well before Ms. Ocasio was implanted with the G2 filter, Bard possessed studies showing that the G2 filter was especially prone to fatigue failure. *See, e.g.*, Doc. 46-2 ("McMeeking/Begley Rpt.") at 18 ("[A May 22, 2007] report warned Bard that the stresses and strains in the filter could exceed safe levels and that therefore the G2 filter would be prone to fatigue failure."); Freeman Aff. at 5 ("[A] review of quarterly failure data indicates that there were early indicators . . . (by 2005, in fact, within 6 months of the introduction of the G2 [filter] in the market) that the device was failing and causing adverse events at a rate that was substantially elevated relative to other IVC filters on the market,

[9] At oral argument, Bard requested that the Court defer ruling on this issue because it intended to seek alternative relief in a separate pretrial motion that could potentially moot this issue. *See* Doc. 121 ("Tr.") at 103-04. The Court declines to defer ruling on this issue, however, because it is ripe for consideration. Bard remains free to seek alternative relief—which it has not done yet—to the extent it is permitted to do so under the applicable rules and the Court's scheduling order.

including the predicate SNF[10] filter."). There is also evidence that, despite possessing this information, Bard failed to properly test and/or redesign the G2 filter to resolve its recognized propensity to fail. *See, e.g.*, Begley Aff. at 2, 56; Hull Rpt. at 4. And, there is evidence that Bard continued to market and sell the G2 filter despite failing to adequately address these known issues. Viewed in the light most favorable to Ms. Ocasio, a jury could find by clear and convincing evidence that Bard intentionally or recklessly disregarded the risk of perforation posed by the G2 filter, which Ms. Ocasio ultimately sustained.

The Court, accordingly, will deny Bard's Motion for Summary Judgment as it relates to Plaintiffs' request for punitive damages. *See Johns-Manville Sales Corp. v. Janssens*, 463 So. 2d 242, 249 (Fla. 1st DCA 1984) ("A legal basis for punitive damages is established in products liability cases where the manufacturer is shown to have knowledge that its product is inherently dangerous to persons or property and that its continued use is likely to cause injury or death, but nevertheless continues to market the product without making feasible modifications to eliminate the danger or making adequate disclosure and warning of such danger."); *accord Tillman*, 2015 WL 1456657, at *36.

IV. CONCLUSION

For the reasons stated above, no genuine issues of material fact exist and Bard is entitled to judgment in its favor as to Count I (failure-to-warn and manufacturing defect); Count II (failure-to-warn); Count IV (manufacturing defect); and Count VI (negligent misrepresentation). Bard is not entitled to summary judgment with regard to Count I (design defect); Count III (design defect)

[10] The "SNF," or "Simon Nitinol Filter," is the predecessor device to the Recovery filter. *See* Hull Rpt. at 2.

or Plaintiffs' claim for punitive damages. Bard, therefore, is also not entitled to summary judgment with regard to Plaintiffs' loss of consortium claim.

It is hereby **ORDERED**:

1. Bard's Motion for Summary Judgment (Doc. 48) is **GRANTED**, as to Count I (failure-to-warn and manufacturing defect); Count II (failure-to-warn); Count IV (manufacturing defect) and Count VI (negligent misrepresentation).
2. The Motion for Summary Judgment is otherwise **DENIED**.
3. Plaintiffs' Fifth Cause of Action is **DISMISSED**, as it was withdrawn by Plaintiffs.
4. Bard's Motion to Strike Plaintiffs' Untimely Expert Opinions of Drs. Begley and Hyman (Doc. 74) is **DENIED, as moot**, to the extent it relates to Dr. Hyman's affidavit;
5. To the extent Bard's Motion to Strike relates to Dr. Begley's affidavit, it is **DENIED**; however, if Plaintiffs wish to offer the information and opinions in Begley's affidavit at trial, they shall produce Dr. Begley for an additional deposition on the information and opinions contained in his affidavit prior to trial, and Bard is permitted to designate a rebuttal expert, if necessary.
6. To avoid piecemeal litigation, a Final Judgment will be entered at the conclusion of this litigation.
7. A telephonic status conference is scheduled for June 19, 2015 at 2:00 p.m.

DONE AND ORDERED in Tampa, Florida on June 3, 2015.

Charlene Edwards Honeywell

Charlene Edwards Honeywell
United States District Judge

Copies to:
Counsel of Record and Unrepresented Parties, if any